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**RAILWAY INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

TB/T 3548-2019

**Strength design and test accreditation specification for rolling
stock-General
(English Translation)**

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Foreword

WS/T 326-2010 "toothpaste effect evaluation" is divided into the following parts.

- Part 1.General principles;
- Part 2.Guidelines for anti-caries efficacy evaluation;
- Part 3.Guidelines for efficacy evaluation on the control of dental plaque or gingivitis;
- Part 4.Guidelines for efficacy evaluation on dentin hypersensitivity.

This is part 3 of WS/T 326.

Clinical trials in this Part references to the clinical trial's design principle guidelines "American Dental Association Scientific Committee - Accreditation Program - Clinical Trial Program Guide, 2003" that was formulated by American Dental Association (ADA).

This Part was proposed by Chinese Stomatological Association.

This Part was approved by Ministry of Health of the People's Republic of China.

Drafting organizations of this Part. School of Stomatology of Peking University, Huaxi School of Stomatology of Sichuan University, School of Stomatology of Peking University, and School of Stomatology of Shanghai Jiaotong University.

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Efficacy evaluation of toothpaste -

Part 3.Guidelines for efficacy evaluation on the control of dental plaque or gingivitis

1 Scope

This Part of WS/T 326 specifies the assessment and evaluation methods of inhibiting dental plaque and (or) reducing the gingival inflammation efficacy.

This Part applies to the toothpaste products that claim, through chemical action, inhibiting dental plaque and reducing gum inflammation; and of which the physiochemical properties and health-safety indicators comply with relevant national standards. The efficacy evaluation of removing or reducing plaque by mechanical scavenging is not within the scope of this Part.

2 Normative References

The following document is essential for the application of this document. For the documents cited with dates, only that edition applies to this document. For undated references, the latest edition (including any amendments) applies to this document.

WS/T 326.1 Efficacy evaluation of toothpaste - Part 1.General principles

3 Terms and Definitions

The terms and definitions defined in Part 1 of WS/T 326 apply to this document.

4.1 in two independent clinical trials, the experimental group is compared with the

control group; when the amount of plaque is reduced and statistically significant, then it indicates that the subject product having inhibiting plaque efficacy.

4.3 When it meets 4.1 and 4.2 at the same time, it indicates that the product meet

the requirements when determining the effect, that the product has the efficacy to inhibit plaque and (or) reduce the gingival inflammation.

5.1.1 It shall adopt the randomized, controlled, blind-design clinical trial method.

When products that contain certain active ingredients is validated for efficacy for the first time, it shall be implemented at least two independent clinical trials.

5.1.4 When there are two (or more) examiners to participate in the trial, it shall adopt a

unified standard through calibration test (based on a more-experienced doctor as the standard); Kappa value shall be above 0.6. If there is only one examiner, he/she shall conduct, before the test, standard compliance rate test.

5.1.5 Control group may be another group of people whose age, sex, plaque and

gingivitis degree are similar to the conditions of experimental group; it may also take the cross-repeat test of the testees; that is, testees are randomly grouped; use the experimental group's products and the control group's products according to a certain order.

5.1.6 It shall clearly specify the use and dosage of the product. It does not require to

change the brushing method of testees.

5.2.1 For test of reducing plaque, before the test, it needs to conduct scaling to the

testees to remove tartar; on the day when test is started, use a rubber polishing cup to remove plaque and debris; then start using the product. If it is under the strict supervision to use the product, then, on the 5th ~ 7th day, it may assess the plaque volume changes; due to the short period, it may adopt crossover experimental, however, it must ensure the adequate washout period.

5.3.1 Testees' selection

Testees are adult male and female who met the inclusion and exclusion criteria of suffering from gingival inflammation; it shall be determined according to product efficacy. The number of test people shall be estimated based on statistical methods

(meet enough statistical power ($\beta = 0.80$) and 95% confidence level), however, the number of cross-experiment people shall not be less than 30 people.

5.4.1 Adopt the plaque index (such as Turesky and other modified Quigley-Hein PI) to

record plaque coverage area and thickness. It shall focus to observe the plaque near the gingival and interproximal area.

5.4.2 It shall check and record the full-mouth all teeth; each tooth shall be checked at

six sites (buccal-mesial, buccal-central, buccal-distal, lingual-mesial, lingual-central, and lingual-distal).

WS/T 326.3-2010

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Part 3.Guidelines for efficacy evaluation on

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